How the Roadsaver stent changed my practice in CAS

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Disclosure

I have the following potential conflicts of interest to report:

✓ Consulting – Boston Scientific, Terumo, Eurocor Tech
Unmet Need In The CAS Market – Sustained Embolic Protection

No stent or EPS protects against late embolization

Table 4. Overview of event rates related to the different stents

<table>
<thead>
<tr>
<th>Stent name</th>
<th>Total population</th>
<th>Symptomatic population</th>
<th>Asymptomatic population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients</td>
<td>All events</td>
<td>Post-procedural events</td>
</tr>
<tr>
<td>X-act</td>
<td>1.9%</td>
<td>1.9%</td>
<td></td>
</tr>
<tr>
<td>Nexstent</td>
<td>3.3%</td>
<td>3.3%</td>
<td></td>
</tr>
<tr>
<td>Wallstent</td>
<td>2.3%</td>
<td>1.2%</td>
<td></td>
</tr>
<tr>
<td>Precise</td>
<td>4.1%</td>
<td>3.1%</td>
<td></td>
</tr>
<tr>
<td>Protégé</td>
<td>3.0%</td>
<td>3.0%</td>
<td></td>
</tr>
<tr>
<td>Acculink</td>
<td>4.2%</td>
<td>3.7%</td>
<td></td>
</tr>
<tr>
<td>Exponent</td>
<td>11.8%</td>
<td>5.9%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>3179</td>
<td>2.83%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

2/3 CAS neuro events (stroke, TIA) are POST-procedural

Eur J Vasc Endovasc Surg Vol 33, Feb 2007
Closed Cell Stents In CAS

Symptomatic Stenosis
(>70 % NASCET)

Curved vessel
long lesion > 1 cm

straight vessel
long lesion > 1 cm

curved vessel
short lesion < 1 cm

Carotid Wallstent™
(Boston Scientific)
n=64 (63.4 %)

Xact™
(Vascular Abbott)
n=16 (15.8 %)

Cristallo Ideale™
(Invatec)
n=21 (20.8 %)

Closed Cell Stents In CAS  
- Clinical outcome and complications

101 pts., symptomatic

<table>
<thead>
<tr>
<th>Complications</th>
<th>during procedure</th>
<th>at 30 days</th>
<th>follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Major stroke</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hyperperfusion syndrome</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TIA</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>myocardial infarction</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

stroke rate 2.9%
Overall death & stroke stroke rate 1% @ 30 days

Cell Size Comparison

Micromesh (375-700 µm)

- Roadsaver
- Stent A
- Stent B
- Stent C
- Stent D
- Stent E
Stent Features & Benefits

Dual Layer Braided Stent with Micro-mesh Technology

**Inner layer**
- Micro-mesh with very small cell size (375-700 µm) limits plaque prolapse and embolic release

**Outer layer**
- **Conformability**: Braided Nitinol design allows for in-vivo stent tapering and conformability to ICA-CCA segments
- **Flexibility**: Closed cell stent with the flexibility of open cell stent, resulting in excellent vessel wall apposition in tortuous anatomy
Dual Layer Stent Designs

CGUARD

TERUMO

GORE
Dual Layer Stent Designs

- double layer micromesh nitinol scaffold, up to 50% deployment full re-sheathable and repositionable; pore size 375µm

6 pts
- Procedure success 100%
- Procedural complications 0%
- 30-day MAE cardiac or cerebrovascular 0%
- 6-months MAE cardiac or cerebrovascular 0%

12 pts
- no ischemia


Dual Layer Stent Designs

- double layer micromesh nitinol scaffold, up to 50% deployment full re-sheathable and repositionable; pore size 375µm

100 pts, multi-center, prospective
- Procedure success 100%
- Procedural complications 0%
- 30-day MAE cardiac or cerebrovascular 2.1%


23 pts, single-center, prospective
- 30-day MAE cardiac or cerebrovascular 0%
- 30-day DWI MRI lesions 0%

Smaller Pore Size – More Material: Enhanced Thrombogenicity?

*165µ

Closed cell stent

Open cell stent

375

500

1050

1900

* Average in lesion at expanded state

Smaller Pore Size – More Material: Enhanced Thrombogenicity?

*165µ

Closed cell stent

Open cell stent

375

500

1050

1900

* Average in lesion at expanded state

Closed cell stent

Open cell stent

* Average in lesion at expanded state

CGUARD

Roadsaver

GORE

* Average in lesion at expanded state
## Dual Layer Stent Designs: Early Reports

**CARENET:** 30 pts, EPDs were used in all procedures
- Procedure success: 100%
- Procedural complications: 0%
- 30-day MAE cardiac or cerebrovascular: 0%


**Clear-Road:** 100 pts, multi-center, prospective
- Procedure success: 100%
- Procedural complications: 0%


**Scaffold-Trial:** 312 pts, multi-center, prospective
- Procedure success: 100%
- Procedural complications: 0%

*Presented at Veith 2017*
Flensburg Dual-Layer Carotid Stents Experience 2014 – 2018 ongoing

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>total</th>
<th>stroke rate (%) @30 days</th>
<th>ISR after 12 months based on US (asymptomatic)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>n=11</td>
<td>n=30</td>
<td>n=30</td>
<td>n=23</td>
<td>n=28</td>
<td>n=122</td>
<td>2/139</td>
<td>5/139</td>
</tr>
<tr>
<td><strong>Symptomatic/ asymptomatic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.4%</td>
<td>3.6%</td>
</tr>
<tr>
<td>n=11</td>
<td>11/0</td>
<td>26/4</td>
<td>23/7</td>
<td>17/14</td>
<td>25/12</td>
<td>102/37</td>
<td>1.4%/0%</td>
<td>1.4%/2.2%</td>
</tr>
<tr>
<td>n=3</td>
<td></td>
<td>n=17</td>
<td>n=11</td>
<td>n=8</td>
<td>n=9</td>
<td>n=17</td>
<td>102/37</td>
<td>1.4%/0%</td>
</tr>
<tr>
<td><strong>symptomatic (acute stroke)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.9%</td>
<td></td>
</tr>
<tr>
<td>n=3</td>
<td>n=8</td>
<td>n=10</td>
<td>n=3</td>
<td>n=8</td>
<td>n=9</td>
<td>n=17</td>
<td>102/37</td>
<td>1.9%</td>
</tr>
<tr>
<td><strong>Tandem lesion</strong></td>
<td>n=3</td>
<td>n=17</td>
<td>n=11</td>
<td>n=8</td>
<td>n=10</td>
<td>n=53</td>
<td>No acute occlusion!!</td>
<td>1/53 asymptomatic</td>
</tr>
<tr>
<td>n=3</td>
<td>n=1</td>
<td>n=3</td>
<td>n=53</td>
<td>n=8</td>
<td>n=10</td>
<td>n=53</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Roadsaver™ CGuard™

Dual Layer CAS: The Flensburg Experience

http://www.diako.de
How do I treat today patients with Roadsaver

Emergency treatment:

• Bridging
  ✓ 0.9mg/kg BW r-tPA

• antiplatelet medication
  Peri-procedural
  ✓ 5000 units Heparine (ACT 250s-300s)
  ✓ 500mg ASA i.v.
  ✓ 300mg Clopidogrel after control (conebeam-)CT, usually @ day 1

Post-procedural
  ✓ 75mg Clopidogrel for 6 months
  ✓ 100mg ASA life-long
How do I treat today patients with Roadsaver

**Elective treatment:**

- antiplatelet medication

**Pre-procedural**
- ✓ 300mg Clopidogrel and 100mg ASA
  (5 days before or loading dose 300mg Clopidogrel)

**Peri-procedural**
- ✓ 5000 units Heparine (ACT 250s-300s)

**Post-procedural**
- ✓ 75mg Clopidogrel for **6 months**
- ✓ 100mg ASA life-long
How do I treat today patients with Roadsaver

• Stent sizing
  ✓ 7mm or 8mm diameter
  ✓ 18mm to 25mm length

• Stent-deployment
  ✓ Continuous

• Stent –post-dilatation
  ✓ 5mm in all cases!!
Dual-Layer Carotid Stents: proven concept of safety


Preparation + ongoing antiplatelet medication
Double layered stents for carotid angioplasty: A meta-analysis of available clinical data


Anna Sannino, MD$^{1,2*}$ | Giuseppe Giugliano, MD, PhD$^{1,2*}$ | Evelina Toscano, MD$^{1,2}$ | Gabriele G. Schiattarella, MD$^{1,2}$ | Anna Franzone, MD, PhD$^{1,2}$ | Tullio Tesorio, MD$^{3}$ | Bruno Trimarco, MD$^{1,2}$ | Giovanni Esposito, MD, PhD$^{1,2}$ | Eugenio Stabile, MD, PhD$^{1,2}$

Roadsaver subgroup demonstrated very low rates of post procedural AEs at 30-day.
299 patients
Death and Stroke Rate 0.02%

<table>
<thead>
<tr>
<th>Event Rate</th>
<th>95% CI</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bosiers et al. 2016</td>
<td>0.02</td>
<td>0.01 / 0.08</td>
</tr>
<tr>
<td>Castagno et al. 2016</td>
<td>0.10</td>
<td>0.01 / 0.67</td>
</tr>
<tr>
<td>Kedev et al. 2015</td>
<td>0.05</td>
<td>0.00 / 0.45</td>
</tr>
<tr>
<td>Nerla et al. 2016</td>
<td>0.00</td>
<td>0.00 / 0.05</td>
</tr>
<tr>
<td>Ruffino et al. 2016</td>
<td>0.02</td>
<td>0.00 / 0.26</td>
</tr>
<tr>
<td>Wissgott et al. 2016</td>
<td>0.04</td>
<td>0.00 / 0.40</td>
</tr>
<tr>
<td><strong>Roadsaver</strong></td>
<td>0.02</td>
<td>0.01 / 0.06</td>
</tr>
</tbody>
</table>

**FIGURE 2** 30-day mortality and stroke rate. Random effects event rate and 95% confidence interval for 30-day mortality and stroke (A) and relative subgroup analysis (B)
ROADSAVER Study

Prospective, single-arm, multi-center, observational study

Primary Outcome measure:
The rates of Major Adverse Events (MAEs) defined as the cumulative incidence of any death or stroke up to 30 days after the index procedure

Study Organization:
Independent Clinical Events Committee (CEC)
Steering Committee (SC)
Sponsored by Terumo Europe
European Medical & Clinical Division (EMCD)
ROADSAVER Study Overview

- 8 active countries
- 26 sites activated
- 23 sites to be activated

226/2000 patients enrolled
Delivery System Features & Benefits

- Fully repositionable with up to 50% deployment, improving stent placement accuracy
- Delivery catheter with flexible distal design to enhance trackability in highly challenging anatomy\(^1\)
- Low profile 5 Fr sheath compatible system enhances the crossability for stenting\(^2\)

\(^1\)Compared to other other stent delivery systems. Roadsaver – the paradigm shift in carotid artery treatment. Giovanni Torsello, Münster, Germany. Presentation on LINC, 26 January 2016, Leipzig, Germany

\(^2\)Compared to other other stent delivery systems. Roadsaver – innovative solutions for CAS. Stefan Müller-Hülsbeck, Flensburg, Germany. Presentation on LINC, 24 January 2017, Leipzig, Germany
Crossing Profile

RoadSaver 7x18

CGUARD 7x30

RoadSaver 7x18

6F
D=2mm
3.14mm²

5F
D=1.67mm
2.19mm²

30% difference!
Unmatched clinical needs?

- The ECA with Roadsaver remains patent @ 6months!
Switching from single to dual layer stent?
Switching from single to dual layer stent?

YES!
Anything to add?

- "We know that with CAS, there are two critical ways to avoid stroke: patient selection and operator experience."

Mark Wholey: J Endovasc Ther 2007; 14: 687-688
How the Roadsaver stent changed my practice in CAS

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